

Remarks:

Reconsideration of the application is requested.

Claims 1 to 24 remain in the application. Claims 1, 3, 4, 10, 15, and 23 have been amended. Claims 25 to 38 have been added.

In item 1 on page 2 of the above-identified Office action, the Examiner objected to the specification because of various informalities. The serial number of the co-owned application has been inserted in the cited paragraphs.

In items 2 to 6 on pages 2 to 4 of the above-identified Office action, claims 1 to 4, 6, 7, 15, 23, and 24 have been rejected as being obvious fully anticipated by Brinkerhoff et al. (U.S. 5,354,312; hereinafter "Brinkerhoff") under 35 U.S.C. § 102.

In items 7 to 11 on pages 4 to 5 of the above-identified Office action, claims 1 to 4, 6, 7 to 11, and 13 to have been rejected as being fully anticipated by Hart et al. (U.S. 6,139,555; hereinafter "Hart") under 35 U.S.C. § 102.

The rejection has been noted and the claims have been amended in an effort to even more clearly define the invention of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a surgical clip applier, including:

- a) a hollow member having a proximal end and a distal end;
- b) a clevis coupled to the distal end of the hollow member;
- c) a first jaw rotatably coupled to the clevis;
- d) a second jaw rotatably coupled to the clevis in opposed relation to the first jaw, at least one of the first and second jaws having an enclosure shaped to fit a surgical clip, the first and second jaws adapted to apply the surgical clip
- e) at least one pull/push wire coupled to the first and second jaws and extending through the hollow member to the proximal end of the hollow member;
- f) actuation means coupled to the proximal end of the hollow member and the proximal end of the first push/pull wire for moving the first push/pull wire through the hollow member to cause a rotation of the first and second jaws about the clevis from an open to a closed position, wherein at least one of the jaws is provided with a plurality of teeth arranged to puncture and damage tissue adjacent to the surgical clip.

Claim 10 calls for, *inter alia*, a surgical clip applier, including:

- a) a hollow member having a proximal end and a distal end;
- b) a clevis coupled to the distal end of the hollow member;

c) a first jaw rotatably coupled to the clevis, the first jaw having a first clip guiding channel terminating in a first anvil;

d) a second jaw rotatably coupled to the clevis in opposed relation to the first jaw, the second jaw having a second clip guiding channel terminating in a second anvil, the first and second jaws adapted to apply a surgical clip with the first and second clip guiding channels;

e) at least one pull/push wire coupled to the first and second jaws and extending through the hollow member to the proximal end of the hollow member; and

f) actuation means coupled to the proximal end of the hollow member and the proximal end of the first push/pull wire for moving the first push/pull wire through the hollow member to cause a rotation of the first and second jaws about the clevis from an open to a closed position.

Claim 15 calls for, *inter alia*, an endoscopic surgical instrument, including:

a) a hollow member having a proximal end and a distal end;

b) a clevis coupled to the distal end of the hollow member;

c) a first end effector rotatably coupled to the clevis and having an enclosure adapted to apply a surgical clip;

d) a first pull/push wire extending through the hollow member to the proximal end of the hollow member;

e) a first linkage including a first rotating element rotatably coupled to the clevis and coupled to the first push/pull wire, and a second element rotatably coupled to the first element and rotatably coupled to the first end effector; and

f) actuation means coupled to the proximal end of the hollow member and the proximal end of the first push/pull wire for moving the first push/pull wire through the hollow member to cause a rotation of the first end effector about the clevis.

Claim 23, calls for, *inter alia*, an endoscopic surgical instrument, including:

- a) a hollow member having a proximal end and a distal end;
- b) a clevis coupled to the distal end of the hollow member;
- c) a first end effector rotatably coupled to the clevis and having an enclosure adapted to apply a surgical clip;
- d) a first pull/push wire extending through the hollow member to the proximal end of the hollow member;
- e) a first linkage including at least one element rotatably coupled to the clevis and coupled to the first push/pull wire and coupled to the first end effector, the first linkage providing mechanical advantage in rotating the first end effector; and
- f) actuation means coupled to the proximal end of the hollow member and the proximal end of the first push/pull wire for moving the first push/pull wire through the hollow member to cause a rotation of the first end effector about the clevis.

Brinkerhoff's grasping instrument does not contain any clips, does not relate to clips, does not apply any clip, and is not involved in a clipping process. Hence, it is not a clip applier nor does it function as one. It is merely a grasper/manipulator used to position a component of a separate device for applying a clip, or to be used as a general-purpose grasper when not being used for component positioning. See, i.e., U.S. Patent 5,269,804 to Bales et al. The Brinkerhoff teeth are provided only for increasing friction when engaging

tissue -- they are not designed or intended to penetrate the tissue. Therefore, it is respectfully submitted that the Examiner's statement on page 3, lines 7 to 10, of the Office action is not correct and that such a statement is a misapplication of the teachings of Brinkerhoff.

In items 3, 4, and 5 rejecting claims 3, 4, 6, 7, and 15, the Examiner states that "Brinkerhoff discloses a device capable of applying surgical clips." As set forth above, this statement is not correct as Brinkerhoff's device does not even relate to clips, let alone grasp or guide a clip. More specifically, Brinkerhoff does not have any kind of clip guiding channels as set forth in claims 3 and 4. Also, Brinkerhoff's device does not have surfaces that ever touch a clip; therefore, it cannot have anvils with a curved surface as set forth in claims 6 and 7.

With regard to the rejection in item 5 of claim 15, it is respectfully submitted that Brinkerhoff is not related to clips, therefore, it cannot have any kind of enclosure adapted to apply a surgical clip. Thus, all of the arguments distinguishing Brinkerhoff apply to claim 15 as well and are hereby incorporated by reference.

Independent claims 10 and 15 of the instant application relate to a double-acting leverage system that increases the closing

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force of the instrument. Prior-art graspers and clip appliers (such as Brinkerhoff, and Hart as well) have only a single-action linkage. This patentable and significant difference is analogous to the difference between simple wire cutters and double-action bolt cutters. Because neither reference discloses or suggests such a configuration, they cannot be said to anticipate the invention of claims 10 and 15.

Finally, with regard to the rejection of claims 23 and 24 in item 6 of the rejection, Brinkerhoff's linkage elements 66, 68 are not coupled to the clevis member 65 (contrast paragraph (e) in claim 23). Rather, the linkage elements 66, 68 ride free within the clevis member 65 and are only joined to the push rod 54 and the jaw members 46, 48. The linkage element 66, 68 do not provide the force/leverage amplification claimed in claims 23 and 24 of the instant application.

The Examiner also rejects claims 1 to 4, 6, 7 to 11 and 13 of the instant application as being anticipated by Hart.

Claims 1 and 10 of the instant application each include "at least one pull/push wire coupled to said first and second jaws and extending through said hollow member to said proximal end of said hollow member . . . [and] actuation means coupled to said proximal end of said hollow member and said proximal end of said first push/pull wire for moving said first push/pull

wire through said hollow member to cause a rotation of said first and second jaws about said clevis from an open to a closed position, wherein at least one of said jaws is provided with a plurality of teeth arranged to puncture and damage tissue adjacent to the surgical clip."

First, Hart does not disclose or suggest the pull/push wire coupled to the first and second jaws. Hart also does not disclose or suggest such a wire extending through a hollow member from the distal end to the proximal end. Because Hart does not have a pull-push wire, Hart cannot be said to disclose or suggest an actuation means coupled to a proximal end of the wire, let alone, one that is also coupled to the proximal end of the hollow member.

False
Col. 7
15-55
does a
tubular
member
count
as a
wire?

Finally, Hart does not disclose or suggest teeth that puncture and damage tissue adjacent to the surgical clip.

Claim 10 of the instant application further provides that the "first jaw ha[s] a first clip guiding channel terminating in a first anvil . . . [a] second jaw having a second clip guiding channel terminating in a second anvil".

Hart teaches a forming curve 64 that deforms the end of the clip 24. See Hart at FIG. 7. Hart specifically describes that this curve is "within each guide slot." Col. 7, lines 23

to 24 (emphasis added by applicants). The anvils of the present invention, in contrast, are disposed beyond the end of the guide slots, specifically, the guiding channel "terminat[es] in" the anvil, an important distinction. See FIGS. 3 to 5 and 9 of the instant application, in particular.

Finally, Hart discloses a "movable shim" (60) that can be moved in a subsequent motion to compress the clip after it is advanced. See col. 9, line 64, to col. 10, line 40. The present invention does not have such a moving part that deforms the clip like that in Hart. Compression under the present invention occurs at the end of the advancement, once the clip has already been advanced onto the tissue.

The invention of the instant application is an improvement over the Hart device. The Hart device seizes tissue and pushes the clip over the tissue without substantially deforming the tissue (see FIG. 3). Thus, the Hart device does not generate adhesion of the tissue after implantation of the clip and, in no way, suggests purposefully piercing the tissue to obtain adhesion. The invention of the instant application, however, purposefully deforms the tissue by folding and piercing the tissue and by engaging the ends of the jaws into the tissue, as set forth on page 10, lines 12 to 13, page 21, lines 9 to 14, of the instant application. The inserted clip is locked in place after piercing by the effector.

Clearly, Brinkerhoff and Hart do not show a surgical clip applier or an endoscopic surgical instrument as recited in claims 1, 10, 15, and 23 of the instant application.

Claims 25 through 38 have been added. Each of the first four pairs of new independent claims respectively find support from original claims 1, 10, 15, and 23. New independent claims 33 through 36 are variations of original claims 15 and 23. Dependent claims 37 and 38 find support from original claims 14 and 22. No new matter has been added.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 10, 15, 23, or 25 through 36. Claims 1, 10, 15, 23, and 25 through 36 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claims 1, 10, 15, or 23.

Finally, applicants appreciatively acknowledge the Examiner's statement that claims 5, 12, and 16 to 22 "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." In light of the above, applicants respectfully believe that

rewriting of claims 5, 12, or 16 to 22 is unnecessary at this time.

In view of the foregoing, reconsideration and allowance of claims 1 to 38 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of two months pursuant to Section 1.136(a) in the amount of \$205.00 in accordance with Section 1.17 is enclosed herewith. The fees of \$504.00 for twelve (12) new independent claims in excess of three and \$126.00 for fourteen (14) new claims in excess of twenty (20) are also enclosed herewith.

Please charge any other fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Lerner and Greenberg, P.A., No. 12-1099.

Respectfully submitted,



For Applicants

GLM:cgm

Gregory L. Mayback
Reg. No. 40,719

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Lerner and Greenberg, P.A.
Post Office Box 2480
Hollywood, FL 33022-2480
Tel: (954) 925-1100
Fax: (954) 925-1101